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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,081	12/16/2005	Gregor John Anderson	PB60389A USW	6103
23347	7590	12/26/2008		
GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B482 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398			EXAMINER WAGGONER, TIMOTHY R	
			ART UNIT 3651	PAPER NUMBER
			NOTIFICATION DATE 12/26/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/561,081	Applicant(s) ANDERSON ET AL.	
	Examiner TIMOTHY R. WAGGONER	Art Unit 3651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,6-34,37-51 and 57-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,6-34,37-51 and 57-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 11/21/2008 with respect to claim 1 and its dependent claims have been fully considered but they are not persuasive. Applicant argues that Gibilisco does not anticipate the limitations of claim one because it dispenser a single pill per an actuation. However the claim as written merely states a predetermined number which given its broadest definition includes single units. There is no limitation in the claim which states clearly that the dispenser can be adjusted or set to different predetermined values. For at least the reasons listed above claim 1 stands rejected and its dependent claims rejected in the 102 based on Gibilisco stand rejected.

Applicant's arguments filed 11/21/2008 with respect to claims 50 and 51 have been fully considered but they are not persuasive. Applicant cites one embodiment of Gibilisco which mentions a locking device which in applicants opinion would preclude the need for an anti tampering sticker or other indicator. However this statement only references a single embodiment and Gibilisco includes multiple embodiments with various means of connecting the dispensing adapter to a container. Furthermore even if there were a locking device that does not preclude tamper indication as there is no key mentioned by Gibilisco the locking is merely a snap fit and not a keyed lock. For at least the reasons listed above claims 50 and 51 stand rejected.

Applicant's arguments filed 11/21/2008 with respect to claims 32-34 and 38 have been fully considered but they are not persuasive. Applicant argues that you can not physically combine Gibilisco and Scarrott to account for each dispensation. However

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103 does not require that the exact devices used to reject the claim to be combinable as is but allows for some leeway in their combination. Further more applicant has limited their arguments to a single embodiment of Scarrott and ignores the embodiment in which only an axial movement is needed to actuate the counter see figures 12-17. For at least the reasons listed above claims 32-34 and 38 stand rejected.

Applicants arguments filed 11/21/2008 with respect to claims 35,36 and 39-46 have been fully considered but they are not persuasive. Applicant argues that Kossoff does not teach the electronic means as claimed and states that Kossoff only teaches mechanical means. However in the embodiment as seen in figures 1A and 1B relies on the input from the solenoid triggers by the device 35 to increment the count and work cooperatively with the device 25 to monitor and limit usage. Further more the trend towards switching from mechanical devices to more electronic devices is well known in the art. For at least the reasons listed above claims 35,36 and 39-46 stand rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,4,6-31,47-49 and 57-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Gibilisco et al. USPN 4,653,668.

Gibilisco discloses a dispensing cap comprising:

(Re claim 1) “a container ... opening” (12.0,12.6 figure 12). “a dispensing module ... covers the access opening” (12.1 figure 12). “internal volume” (12.3 figure 12). “an outlet opening” (12.5 figure 12). “a dispensing mechanism which operates to dispense a predetermined number” (12.7 figure 12).

(Re claim 4,6,57) Gibilsco discloses various caps and closures as claimed (“screw cap”, col 5 lines 50-56).

(Re claim 7) “dispensing mechanism is adapted in use to dispense the unit products one at a time” (12.7 figure 12).

(Re claim 8) “predetermined number is one” (12.7 figure 12).

(Re claim 9) “dispensing mechanism is manually actuatable by a user” (figure 2).

(Re claim 10) “non-dispensing mode ... dispensing mode” (figures 5,6).

(Re claim 11) “a biasing structure” (7,8 figure 5).

(Re claim 12) “shut state ... open state” (figures 5,6).

(Re claim 13) “one at a time” (figure 5,6).

(Re claim 14) “channel adapted to cause the unit products to be conveyed” (3,4 figure 5).

(Re claim 15) “in a common predetermined orientation of the unit product” (figure 5,6)..

(Re claim 16) “channel ... predetermined orientation” (3,4 figure 6).

(Re claim 17) “funnel-like ... channel” (3 figure 5,6).

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(Re claim 18) “channel is a length sufficient that a queue of unit products” (figure 9).

(Re claim 19) “shut state ... open state ... blocked ... un-blocked” (figures 5,6).

(Re claim 20) “gate mechanism ... predetermined number ... front of queue” (figure 11).

(Re claim 21) “unblocks the channel in front ... blocks the channel behind” (figure 5,6).

(Re claim 22) “displaces the portion of the queue disposed behind” (figure 6).

(Re claim 23) “manually-engagable actuator for actuating the dispensing mechanism” (2 figure 5)..

(Re claim 24) “actuator protrudes from the dispensing module” (2 figure 5).

(Re claim 25) “actuator is displaceable into the dispensing module” (2 figure 6).

(Re claim 26) “actuated by a hand of a user ... dispensed into that hand” (figure 3,2).

(Re claim 27) “pushing the module into a user’s palm is able to cause actuation” (figure 2).

(Re claim 28) “open state ... shut state ... actuator forms at least part of gate” (figure 29).

(Re claim 29) “including the unit products” (figure 4).

(Re claim 30) “unit products are pharmaceuticals” (figure 4).

(Re claim 31) “pharmaceutical products are oral dosage forms” (figure 4).

(Re claim 47) “products are gravity-fed from the container to the dispensing module” (figure 5).

(Re claim 48) “gravity-fed to the outlet opening” (figure 5,6).

(Re claim 49) “tamper-evidence structure is provided to show whether the dispensing module” (31.11 figure 31).

(Re claim 58-61) a closure which closes the dispensing mechanism and disables the Actuation mechanism which defines the outlet opening. (31.9 figure 31).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gibilisco et al. USPN 4,653,668.

A label connected to a dispensing member and a container for use as a tamper evident seal is common in pharmaceutical goods and even in food product containers. As such it would be obvious to include such on Gibilisco.

Claims 32-34, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gibilisco in view of Scarrott et al. USPN 6,761,161.

Gibilisco discloses the dispenser as claimed in claim 1.

Gibilisco does not disclose a counter actuated by the dispensing of a unit.

Scarrott teaches a counter with graphical indicator which is actuated when the device is pressed down to dispense.

It would be obvious to one skilled in the art to modify the dispenser of Gibilisco to include a counter as taught by Scarrott because it allows the user to track usage.

Claims 39-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gibilisco/Scarrott further in view of Kossoff et al. USPN 5,300,042.

Gibilisco/Scarrott teach a dispenser with means to count dispenses.

Gibilisco/Scarrott does not disclose an electronic display or timer or electronic switch.

Kossoff teaches an electronic display, a timer between uses, electronic switch, and alarm.

It would be obvious to one skilled in the art to modify the dispenser of Gibilisco/Scarrott to include the digital counter, switch, alarm and timer as taught by Kossoff because improved means for tracking usage and reminding user to take their medicine.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY R. WAGGONER whose telephone number is (571)272-8204. The examiner can normally be reached on Mon-Thu 8am-2pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gene Crawford can be reached on (571) 272-6911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gene Crawford/
Supervisory Patent Examiner, Art
Unit 3651

TRW